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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,872	09/28/2001	Mark Roby	11396 (203-3054)	3462

7590

12/23/2005

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT

PAPER NUMBER

1762

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,872

Applicant(s)

ROBY, MARK

Examiner

Jennifer K. Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/6/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/02; 6/24/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>add'l IDS maildate: 3/21/02</u> . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-17 in the reply filed on 10/6/2005 is acknowledged. The traversal is on the ground(s) that separate classification is not proof of divisibility, that there would not be serious burden, and that the searches are felt to be co-extensive. This is not found persuasive because a method of coating and a coated suture are different inventions. Examination of both would be burdensome. The art for one invention is different than that for the other, the searches are different, and different issues during prosecution will arise.

The considerations used for examining method claims are different than those used for examining product claims. Product claims are examined based on the properties of the final article produced, not on the method used to create the article. When examining a claim directed to a method of coating, it is necessary to find the process steps of the coating method. When examining claims directed to a coated product, the applicable art includes art directed to Applicant's final coated substrate produced by any method. Applicable references for a method of coating do not necessarily encompass all the fields of search required for product claims and therefore there is an additional burden in examining two classes of invention. For example, the prior art used to reject the product claims would not necessarily contain the method steps of the coating process claims.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-3, 5-13, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora et al. (6,613,432) in view of Totakura (5,383,903).

Zamora teaches a method of coating blood- and tissue-contacting medical substrates by plasma polymerizing a hydrocyclosiloxane monomer, meeting the formula of Applicant, thereon (abstract; col. 4, lines 30-40). Zamora also teaches the use of alkylene oxide as a further layer (see below for details).

Zamora does not specifically teach coating sutures, however, Zamora teaches that his coating is suitable on temporarily implantable medical substrates which contact blood and tissue that may be made of polymers, such as polyethylene (col. 10, lines 9-13). This teaching is inclusive of sutures.

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Additionally, Totakura is cited for teaching a method of coating polyethylene or polypropylene (both polyolefins) sutures with siloxane and alkylene oxide (abs; col. 2, lines 50).

Since Zamora and Totakura both teach coating blood- and tissue-contacting medical substrates made of polyethylene with siloxane and alkylene oxide coatings and since Totakura teaches that such coatings are placed on sutures, Totakura would have reasonably suggested coating sutures by the method of Zamora. It would have been obvious to one of ordinary skill in the art to use the teachings of Totakura in the method of Zamora to provide Zamora with another suitable medical substrate for coating by the method of Zamora.

Regarding claims 2 and 11, Zamora teaches the specific hydrocyclosiloxanes claimed (col. 6, lines 1-7).

Regarding claims 2, 3, 5, 6, 12, 14, and 15 Zamora teaches that the coating further comprises an amine group introduced by plasma polymerization of a gas containing the monomer N-trimethylsilyl-allylamine (col. 5, lines 9-18; col. 14, line 48).

Regarding claims 7-8 and 16-17, Zamora teaches that the amine-grafted hydrocyclosiloxane membranes may be reacted with carbonate polyoxyalkylenes, such as polyoxyethylene bis-(N-hydroxybenzotriazolyl) carbonate (col. 7, line 40; col. 15, lines 9-30).

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Regarding claim 9, both references teach polyethylene substrates and Totakura teaches sutures made of polypropylene, both well-known polyolefins. It would have been obvious to use the polypropylene of Totakura in the method of Zamora as a suitable polyolefin for coating with siloxanes and alkylene oxides.

5. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora in view of Totakura as applied to claims 1-3, 5-12, and 14-17 above, and further in view of Hu (5,463,010).

Zamora in view of Totakura teach that which is disclosed above, namely, plasma polymerizing a suture with the hydrocyclosiloxane monomers and then plasma grafting N-trimethylsilyl-allylamine monomers thereto. What this combination fails to teach is the plasma co-polymerization of the two.

Hu teaches coating polypropylene fibers or other medical devices which come into contact with blood with a coating formed by plasma co-polymerization of the same hydrocyclosiloxane and N-trimethylsilyl-allylamine monomers as Zamora. Since Zamora in view of Totakura teach plasma grafting one monomer onto the other and Hu teaches plasma co-polymerizing the two monomers together on similar substrates for use in similar applications, Hu would have reasonably suggested to one of ordinary skill in the art to interchange the plasma grafting of Zamora in view of Totakura with his copolymerization method with the expectation of similar and successful results on similar substrates for use in the body for contact with blood and tissue.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Winters, 5,338,770, is cited for teaching the coating of a polypropylene medical substrate with siloxane, then an amine group, then an ethylene oxide.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Mondays & on Tuesday and Wednesday afternoons.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Michener
Primary Examiner
Art Unit 1762
December 19, 2005